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09/182,645 10/30/98 LI

J 23737

EXAMINER

HM12/0411

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WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

04/11/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/182,645

Applicant(s)

LI ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-25, 28-31 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26, 27 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Applicant's election with traverse of the invention of group II, claims 26-37 and species of group IIB, process of using a composition employing lignin glucoside in Paper No. 9 submitted on Feb. 10, 2000 is acknowledged. The traversal is on the ground(s) that it is unclear how the search for the entire subject matter would be an undue burden on the examiner. This is not found persuasive because these inventions are distinct and the search required for the process of group II is not required for the composition of group I. Note that the search herein is not limited to patent files. Further, the claims are drawn to the employment of an array of distinct species of compounds, the search for all of which would present an undue burden on the examiner as discussed in the restriction requirement mailed Dec. 1, 1999.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-25, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 28-31 and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 submitted on Feb. 1, 2000.

The claims have been examined insofar as they read on the elected invention and species.

### ***Disclosure Objection***

3. The disclosure is objected to because of the following informalities:  
page 23, line 9 "PARG" should be "PARP"

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Page 101, line 12 "inhibitom" should be "inhibitors"

Appropriate correction is required.

***Claim Rejection 35 U.S.C. -112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "tannin glycoside" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections 35 U.S.C - 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 26,27 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanuma (AB and AC) in view of both Wielckens et al. (BQ), and Wachsman (BO).

Tanuma (AB) teach a lignin glycoside , an inhibitor of poly(ADP-ribose)glycohydrolase, having following properties:

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- i) Lignin and polysaccharide are bonded,
  - ii) the molecular weight is 8000 to 10000,
  - iii) the bonding ration of lignin and polysaccharide is 1:1 or 2:1,
  - iv) polysaccharide is composed of 10-20 % of uronic acid and 80-90 % of neutral sugar.
- See, particularly, the claims. The lignin glycoside can be obtained from pine corn, tea, grass dogwood. See, particularly, page 4, lines 20-21 of the translated copy. The lignin glycoside comprises the structure claimed in claim 33 of instant application. See page 12 of the translated copy.

Tanuma (AC) also teach another lignin glycoside, an inhibitor of poly(ADP-ribose)glycohydrolase, having following properties:

- i) Lignin and polysaccharide are bonded,
  - ii) the molecular weight is 6000 to 14000,
  - iii) the bonding ration of lignin and polysaccharide is 1:1 or 2:1,
  - iv) polysaccharide is composed of 30-40 % of uronic acid and 60-70 % of neutral sugar.
- See, particularly, the claims. The lignin glycoside can be obtained from pine cone, tea and grass dogwood etc. See, particularly, page 5, lines 2-4. Tanuma further teaches a process of employ the lignin glycoside for treating poly(ADP-ribose)glycohydrolase related diseases. See, particularly, page 5, lines 15-36. (translated copy).

Tanuma do not specifically teach the employment of the lignin glycoside for treating disease directly related to the activity of poly(ADP-ribose)polymerase, e.g., cellular energy depletion, apoptosis or neurological disorder.

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However, Wachsman teaches that inhibitor of poly(ADP-ribose)glycohydrolase will retard apoptosis. See, particularly, page 30, left column, lines 11-13. Wachsman also teach depletion of intracellular NAD will result depletion of cellular energy. See, page 30, right column. Wielckens et al. teach that the depletion of NAD is caused by drastic stimulation of poly(ADP-ribose) turnover. The poly(ADP-ribose) turnover is due to the high activity of both poly(ADP-ribose)polymerase and poly(ADP-ribose)glycohydrolase. See, particularly, page 12876, right column.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lignin glycosides of Tanuma or the like and the process of Tanuma for treating or preventing diseases or conditions related to apoptosis or for decreasing cellular energy depletion.

A person of ordinary skill in the art would have been motivated to employ lignin glycosides of Tanuma or the like and the process of Tanuma for treating or preventing diseases or conditions related to apoptosis or for decreasing cellular energy depletion because the lignin glycoside is a known poly(ADP-ribose)glycohydrolase inhibitor, poly(ADP-ribose)glycohydrolase inhibitors are known for retarding apoptosis and high activity of poly(ADP-ribose)glycohydrolase is responsive for the high turnover of poly(ADP-ribose) and consequently responsive for NAD depletion and cellular energy depletion. Further, since poly(ADP-ribose)polymerase and poly(ADP-ribose)glycohydrolase work in concert in the process of poly(ADP-ribose) turnover, it is reasonably expected that inhibiting one enzyme will

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downregulate the activity of the other, i.e., inhibiting poly(ADP-ribose)glycohydrolase will downregulate the activity of poly(ADP-ribose)polymerase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

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March 28, 2000

  
MINNA MOEZIE  
PRIMARY EXAMINER